

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF ALABAMA  
NORTHERN DIVISION

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MARIE PERSON,

Plaintiff,

v.

ELI LILLY AND COMPANY; and  
YOLANDA MCCAIN, Sales  
Representative, and FICTITIOUS  
DEFENDANTS A, B, C, D, E, and F,  
being those persons, sales representatives,  
firms or corporations, whose fraud,  
scheme to defraud, negligence, and/or  
other wrongful conduct caused or  
contributed to the Plaintiff's injuries and  
damages, and whose true names and  
identities are presently unknown to the  
Plaintiff but will be substituted by  
amendment when ascertained,

Defendants.

CASE NO.: 2:06cv465-SRW

JURY TRIAL DEMANDED

**ANSWER OF DEFENDANT YOLANDA MCCAIN  
TO PLAINTIFF'S COMPLAINT**

Defendant Yolanda McCain ("McCain"), by her counsel, hereby responds to plaintiff's Complaint as follows:

**STATEMENT OF FACTS**

1. McCain is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 1 of the Complaint.
2. McCain admits that Lilly is a corporation organized and existing under the laws of the State of Indiana, with its principal place of business in Indianapolis, Indiana. By way of further response, to the extent the allegations contained in Paragraph 2 of the Complaint are

directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

3. The allegations contained in Paragraph 3 of the Complaint are directed at parties other than answering Defendant. McCain refers to the response of those parties. To the extent an answer is required, McCain is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 3 of the Complaint.

4. The allegations contained in Paragraph 4 of the Complaint are directed at parties other than answering Defendant. McCain refers to the response of those parties. To the extent an answer is required, McCain is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 4 of the Complaint.

5. McCain is without knowledge as to plaintiff's meaning of the term "at all times relevant," and therefore denies the allegations contained in Paragraph 5 of the Complaint. By way of further response, McCain denies allegations contained in Paragraph 5 of the Complaint, except admits that (i) she was employed as a sales representative of Eli Lilly and Company, and (ii) she provided approved information to physicians about certain prescription medicines sold by Lilly, including Zyprexa.

6. McCain is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 6 of the Complaint. To the extent the allegations contained in Paragraph 6 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

7. McCain admits that plaintiff refers collectively to all Defendants named in this action as "Defendants."

8. McCain is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 8 of the Complaint, except admits that this court has jurisdiction pursuant to 28 U.S.C. § 1332. To the extent the allegations contained in Paragraph 6 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

9. McCain denies the allegations contained in Paragraph 9 of the Complaint, except admits that (i) Zyprexa is approved by the FDA for the “treatment of schizophrenia,” “the treatment of acute mixed or manic episodes associated with Bipolar I disorder” and maintenance monotherapy for bipolar disorder; (ii) Zyprexa with Lithium or Valproate, is indicated, in combination, for the short-term treatment of acute manic episodes associated with Bipolar I disorder; and (iii) Zyprexa is a psychotropic agent that belongs in the thienobenzodiazepine class of medications also known as “atypical antipsychotics.” To the extent the allegations contained in Paragraph 9 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

10. McCain denies the allegations contained in Paragraph 10 of the Complaint.

11. McCain denies the allegations contained in Paragraph 11 of the Complaint.

12. McCain is without knowledge as to plaintiff’s meaning of the term “at all times relevant,” and therefore denies the allegations contained in Paragraph 12 of the Complaint. By way of further response, McCain admits that (i) she was employed as a sales representative of Eli Lilly and Company; and (ii) she provided approved information to physicians about certain prescription medicines sold by Lilly including Zyprexa. To the extent the allegations contained

in Paragraph 12 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

13. McCain is without knowledge as to plaintiff's meaning of the term "total profits", and therefore denies the allegations contained in Paragraph 13 of the Complaint.

14. McCain denies the allegations contained in Paragraph 14 of the Complaint, except admits that (i) Zyprexa is approved by the FDA for the "treatment of schizophrenia," "the treatment of acute mixed or manic episodes associated with Bipolar I disorder" and maintenance monotherapy for bipolar disorder; and (ii) Zyprexa with Lithium or Valproate is indicated, in combination, for the short-term treatment of acute manic episodes associated with Bipolar I disorder. To the extent the allegations contained in Paragraph 14 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

15. McCain denies the allegations contained in Paragraph 15 of the Complaint. To the extent the allegations contained in Paragraph 15 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

16. McCain denies the allegations contained in Paragraph 16 of the Complaint. To the extent the allegations contained in Paragraph 16 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

17. McCain denies the allegations contained in Paragraph 17 of the Complaint. To the extent the allegations contained in Paragraph 17 of the Complaint are directed

at parties other than answering Defendant, answering Defendant refers to the response of those parties.

18. McCain admits that medical literature reporting on medical research involving Zyprexa is published in multiple medical journals, but denies plaintiff's description of the literature to the extent that it conflicts with such literature. McCain denies the remaining allegations contained in Paragraph 18 of the Complaint. To the extent the allegations contained in Paragraph 18 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

19. McCain is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 19 of the Complaint. To the extent the allegations contained in Paragraph 19 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

20. McCain denies the allegations contained in Paragraph 20 of the Complaint. To the extent the allegations contained in Paragraph 20 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

21. McCain denies the allegations contained in Paragraph 21 of the Complaint. To the extent the allegations contained in Paragraph 21 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

**ANSWERING COUNT I**  
**(STRICT LIABILITY IN TORT, FAILURE TO WARN)**

22. McCain incorporates by reference, as though fully set forth herein, its answer to each and every allegation contained in each Paragraph of the Complaint.

23. McCain denies the allegations contained in Paragraph 23 of the Complaint. To the extent the allegations contained in Paragraph 23 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

24. McCain denies the allegations contained in Paragraph 24 of the Complaint. To the extent the allegations contained in Paragraph 24 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

25. McCain denies the allegations contained in Paragraph 25 of the Complaint, except admits that information regarding the safety profile of Zyprexa was contained in the FDA-approved Package Insert for Zyprexa. To the extent the allegations contained in Paragraph 25 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

26. McCain denies the allegations contained in Paragraph 26 of the Complaint. To the extent the allegations contained in Paragraph 26 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

27. McCain denies the allegations contained in Paragraph 27 of the Complaint. To the extent the allegations contained in Paragraph 27 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

**ANSWERING COUNT II**

**(Alabama Extended Manufacturer's Liability Doctrine)**

28. McCain incorporates by reference, as though fully set forth herein, its answer to each and every allegation contained in each Paragraph of the Complaint.

29. McCain denies the allegations contained in Paragraph 29 of the Complaint. McCain is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 29 of the Complaint relating to the condition of Zyprexa when it reached consumers. To the extent the allegations contained in Paragraph 29 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

30. McCain denies the allegations contained in Paragraph 30 of the Complaint. To the extent the allegations contained in Paragraph 30 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

31. McCain denies the allegations contained in Paragraph 31 of the Complaint. To the extent the allegations contained in Paragraph 31 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

32. McCain denies the allegations contained in Paragraph 32 of the Complaint. To the extent the allegations contained in Paragraph 32 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

**ANSWERING COUNT III**  
**(NEGLIGENCE)**

33. McCain incorporates by reference, as though fully set forth herein, its answer to each and every allegation contained in each Paragraph of the Complaint.

34. McCain is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 34 of the Complaint. To the extent the allegations contained in Paragraph 34 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

35. McCain denies the allegations contained in Paragraph 35 of the Complaint. To the extent the allegations contained in Paragraph 35 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

36. McCain denies the allegations contained in Paragraph 36 of the Complaint. To the extent the allegations contained in Paragraph 36 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

37. McCain denies the allegations contained in Paragraph 37 of the Complaint. To the extent the allegations contained in Paragraph 37 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

38. McCain denies the allegations contained in Paragraph 38 of the Complaint. To the extent the allegations contained in Paragraph 38 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.



**ANSWERING COUNT IV**  
**(BREACH OF IMPLIED WARRANTY)**

39. McCain incorporates by reference, as though fully set forth herein, its answer to each and every allegation contained in each Paragraph of the Complaint.

40. McCain is without knowledge as to plaintiff's meaning of the term "at all times relevant hereto", and therefore denies the allegations contained in Paragraph 40 of the Complaint. By way of further response, McCain admits only that (i) she was employed as a sales representative of Eli Lilly and Company; and (ii) she provided approved information to physicians about certain prescription medicines sold by Lilly including Zyprexa. To the extent the allegations contained in Paragraph 40 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

41. McCain is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 41 of the Complaint. To the extent the allegations contained in Paragraph 41 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

42. McCain denies the allegations contained in Paragraph 42 of the Complaint, except admits that information regarding the safety profile of Zyprexa was contained in the FDA-approved labeling for Zyprexa. To the extent the allegations contained in Paragraph 44 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

43. McCain denies the allegations contained in Paragraph 43 of the Complaint. To the extent the allegations contained in Paragraph 43 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

**ANSWERING COUNT V**  
**(BREACH OF EXPRESS WARRANTY)**

44. McCain incorporates by reference, as though fully set forth herein, its answer to each and every allegation contained in each Paragraph of the Complaint.

45. McCain denies the allegations contained in Paragraph 45 of the Complaint. To the extent the allegations contained in Paragraph 45 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

46. McCain denies the allegations contained in Paragraph 46 of the Complaint except admits that information regarding the safety profile of Zyprexa was contained in the FDA-approved labeling for Zyprexa. To the extent the allegations contained in Paragraph 46 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

47. McCain denies the allegations contained in Paragraph 47 of the Complaint. To the extent the allegations contained in Paragraph 47 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

48. McCain denies the allegations contained in Paragraph 48 of the Complaint. To the extent the allegations contained in Paragraph 48 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

**ANSWERING COUNT VI**  
**(FRAUD)**

49. McCain incorporates by reference, as though fully set forth herein, its answer to each and every allegation contained in each Paragraph of the Complaint.

50. McCain denies the allegations contained in Paragraph 50 of the Complaint. To the extent the allegations contained in Paragraph 50 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

51. McCain denies the allegations contained in Paragraph 51 of the Complaint. To the extent the allegations contained in Paragraph 51 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

52. McCain denies the allegations contained in Paragraph 52 of the Complaint. To the extent the allegations contained in Paragraph 52 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

53. McCain denies the allegations contained in Paragraph 53 of the Complaint, except McCain is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this Paragraph relating to (i) the reliance of plaintiff or plaintiff's physicians; and (ii) whether plaintiff used Zyprexa. To the extent the allegations contained in Paragraph 53 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

54. McCain denies the allegations contained in Paragraph 54 of the Complaint. To the extent the allegations contained in Paragraph 54 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

55. McCain denies the allegations contained in Paragraph 55 of the Complaint. To the extent the allegations contained in Paragraph 55 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

**ANSWERING COUNT VII**  
**(NEGLIGENT MISREPRESENTATION)**

56. McCain incorporates by reference, as though fully set forth herein, its answer to each and every allegation contained in each Paragraph of the Complaint.

57. McCain is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 57 of the Complaint. To the extent the allegations contained in Paragraph 57 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

58. McCain denies the allegations contained in Paragraph 58 of the Complaint. To the extent the allegations contained in Paragraph 58 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

59. McCain denies the allegations contained in Paragraph 59 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 59 of the Complaint relating to plaintiff or plaintiff's physicians. To the extent the allegations contained in Paragraph 59 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

60. McCain denies the allegations contained in Paragraph 60 of the Complaint. To the extent the allegations contained in Paragraph 60 of the Complaint are directed

at parties other than answering Defendant, answering Defendant refers to the response of those parties.

61. McCain denies the allegations contained in Paragraph 61 of the Complaint. To the extent the allegations contained in Paragraph 61 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

62. McCain denies the allegations contained in Paragraph 62 of the Complaint. To the extent the allegations contained in Paragraph 62 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

63. McCain denies the allegations contained in Paragraph 63 of the Complaint. To the extent the allegations contained in Paragraph 63 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

64. McCain denies the allegations contained in Paragraph 64 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this Paragraph relating to plaintiff and plaintiff's physicians. To the extent the allegations contained in Paragraph 64 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

65. McCain denies the allegations contained in Paragraph 65 of the Complaint. To the extent the allegations contained in Paragraph 65 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

**ANSWERING COUNT VIII**  
**(FRAUD BY CONCEALMENT)**

66. McCain incorporates by reference, as though fully set forth herein, its answer to each and every allegation contained in each Paragraph of the Complaint.

67. McCain denies the allegations contained in Paragraph 67 of the Complaint. To the extent the allegations contained in Paragraph 67 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

68. McCain denies the allegations contained in Paragraph 68 of the Complaint. To the extent the allegations contained in Paragraph 68 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

69. McCain denies the allegations contained in Paragraph 69 of the Complaint. To the extent the allegations contained in Paragraph 69 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

70. McCain denies the allegations contained in Paragraph 70 of the Complaint. To the extent the allegations contained in Paragraph 70 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

71. McCain denies the allegations contained in Paragraph 71 of the Complaint. To the extent the allegations contained in Paragraph 71 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

72. McCain denies the allegations contained in Paragraph 72 of the Complaint. To the extent the allegations contained in Paragraph 72 of the Complaint are directed at parties other than answering Defendant, answering Defendant refers to the response of those parties.

WHEREFORE, defendant Yolanda McCain requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that McCain be awarded the costs, disbursements, and attorney's fees incurred in the defense of this action, and that she be granted any other relief to which she may be entitled.

#### **PREAMBLE TO AFFIRMATIVE DEFENSES**

Defendant Yolanda McCain, by her counsel, pleading in the affirmative and without prejudice to her other pleadings, states the following affirmative defenses. By virtue of asserting additional defenses, McCain does not assume any burden of proof not otherwise legally assigned to her.

McCain reserves the right to rely upon any of the following or any additional defenses to each claim for relief asserted by plaintiffs to the extent that such defenses are supported by information developed through discovery or by evidence at trial.

#### **FIRST AFFIRMATIVE DEFENSE**

The Complaint fails to state a claim upon which relief can be granted against McCain.

#### **SECOND AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred, in whole or in part, by the statute of limitations.

#### **THIRD AFFIRMATIVE DEFENSE**

Venue is improper in this judicial district.

**FOURTH AFFIRMATIVE DEFENSE**

Some or all of plaintiff's claims are barred by the learned intermediary and/or sophisticated user doctrines. At all relevant times herein, plaintiff's prescribing physicians were in the position of learned intermediaries and/or sophisticated purchasers, fully knowledgeable and informed with respect to the risks and benefits of Zyprexa®.

**FIFTH AFFIRMATIVE DEFENSE**

The injuries, damages, and losses alleged in the Complaint, none being admitted, were caused in whole or in part by the negligence of the plaintiff and/or others, over whom McCain exercised no control, had no opportunity to anticipate or right to control, and with whom McCain had no legal relationship by which liability could be attributed to her because of the actions of the plaintiff and/or others.

**SIXTH AFFIRMATIVE DEFENSE**

Plaintiff's alleged loss, damage, injury, harm, expense, diminution, or deprivation alleged, if any, was caused in whole or in part by plaintiff's failure to exercise reasonable care and diligence to mitigate her alleged damages.

**SEVENTH AFFIRMATIVE DEFENSE**

Any and all damages alleged in the Complaint may have been caused by misuse of the product, failure to use the product properly, or negligent use of the product, and therefore the risk was assumed.

**EIGHTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are preempted by federal law in that Zyprexa® was manufactured and labeled in a manner consistent with the state of the art at the pertinent time and approved by the FDA.



**NINTH AFFIRMATIVE DEFENSE**

Any negligent conduct of McCain, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of the injuries alleged in the Complaint.

**TENTH AFFIRMATIVE DEFENSE**

The plaintiff is barred from recovering any damages by virtue of the fact that there was no practical or technically feasible alternative design or formulation that would have prevented the harm alleged by the plaintiff without substantially impairing the usefulness or intended purpose of the subject product.

**ELEVENTH AFFIRMATIVE DEFENSE**

Some or all of plaintiff's claims are barred by the doctrines concerning unavoidably unsafe products, including, but not limited to, the operation of comments j and k to Section 402A of the Restatement (Second) of Torts and/or the Restatement (Third) of Torts.

**TWELFTH AFFIRMATIVE DEFENSE**

Plaintiff's breach of warranty claims are barred because McCain is not a seller; plaintiff failed to give timely notice of any alleged breach of warranty to McCain; plaintiff did not reasonably rely upon any alleged warranty; plaintiff failed to satisfy all conditions precedent or subsequent to the enforcement of such warranty; and the warranty was appropriately disclaimed, excluded or modified.

**THIRTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part by the applicable provisions of the United States Constitution, the Alabama Constitution and/or the applicable Constitution of any other State or Commonwealth of the United States whose laws might be deemed controlling in

this case. These provisions include, but are not limited to, the First Amendment to the Constitution of the United States and/or Article I, Section 4 of the Constitution of the State of Alabama because McCain's commercial speech regarding Zyprexa® was neither false nor misleading.

#### **FOURTEENTH AFFIRMATIVE DEFENSE**

McCain alleges that plaintiff was fully informed of the risks of the use of the product made the subject of this action by the treating physician, and the informed consent given by the plaintiff is pleaded as an affirmative defense.

#### **FIFTEENTH AFFIRMATIVE DEFENSE**

Upon information and belief, the plaintiff had full knowledge, or in the exercise of reasonable diligence would have had, of the risks and possible adverse side effects pertaining to the use of the subject product, as well as the risks relative to the administering of the subject product into the plaintiff's person, and all or part of the alleged injuries, damages, and/or losses (if any) sustained by the plaintiff arose from and were caused by risks of which the plaintiff was so aware, and such risks were accepted and assumed by the plaintiff. McCain possessed no duty to warn the plaintiff, and, upon information and belief, possessed no ability to warn the plaintiff directly, and had no contact with the plaintiff. For these reasons, any recovery against McCain should be diminished, reduced, offset, or barred in accordance with the principles of assumption of the risk.

#### **SIXTEENTH AFFIRMATIVE DEFENSE**

All products in any way connected with McCain are defect-free and not unreasonably dangerous. Such products fully comply with the products liability standard of Alabama.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

Upon information and belief, some or all of the injuries alleged in the Complaint were caused by preexisting medical conditions, subsequent medical conditions, and the natural course of those conditions of the plaintiff, by an idiosyncratic reaction, operation of nature, or act of God, for which McCain is not responsible.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claim for punitive damages violates, and it is therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America on grounds including the following:

a. It is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose punitive damages, which are penal in nature, against a civil defendant upon the plaintiff satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;

b. Procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution;

c. The procedures pursuant to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against defendant, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;

d. The procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;

e. The procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

f. The procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

g. The procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution;

h. An award of punitive damages to plaintiff in this action would constitute a deprivation of property without due process of law; and

i. The procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

#### **NINETEENTH AFFIRMATIVE DEFENSE**

With respect to plaintiff's demand for punitive or exemplary damages, McCain specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damages awards, including but not limited to, those standards of limitation which arose in BMW of North America v. Gore, 517 U.S. 559 (1996), Cooper Industries, Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424 (2001), and State Farm Mutual Automobile Ins. Co. v. Campbell, 538 U.S. 408 (2003).

**TWENTIETH AFFIRMATIVE DEFENSE**

Punitive damages awards in Alabama are unconstitutional because they are penal in nature, yet defendants in civil action are not awarded the same procedural safeguards accorded to criminal and other defendants under the Fourth, Fifth, Sixth, Eighth, and Fourteenth Amendments to the United States Constitution. Therefore, the plaintiff cannot recover punitive damages.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

Punitive damages awards in Alabama are not governed by any specific or adequate standards, are not based upon rational distinctions, do not serve any legitimate state interest, are necessarily vague and arbitrary, and therefore are in violation of the due process and equal protection provisions of the Fifth, Eighth, and Fourteenth Amendments to the United States Constitution, as well as those of Article I, Sections 1, 6, and 22 of the Alabama Constitution. Therefore, the plaintiff cannot recover punitive damages.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

The plaintiff's claims for punitive damages are barred by § 6-11-20 and § 6-11-27 of the Alabama Code.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

McCain affirmatively pleads and avers the protections afforded her by § 6-11-21 of the Alabama Code.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction, in that the Food and Drug Administration of the United States Department of Health and Human Services ("FDA") is charged under the

law with regulating prescription drugs, including Zyprexa®, and is specifically charged with determining the content of the warnings and labeling for prescription drugs. The granting of the relief prayed for in the plaintiff's Complaint would impede, impair, frustrate or burden the effectiveness of such federal law and would violate the Supremacy Clause (Art. VI, cl. 2) of the United States Constitution.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

To the extent plaintiff's claims are based on alleged misrepresentations made to the FDA, such claims are barred pursuant to Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001).

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

The alleged injuries to plaintiff, if any, were caused, in whole or in part, by plaintiff's own contributory negligence, and are therefore barred.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

Any verdict or judgment rendered against McCain must be reduced by those amounts that have been, or will be, with reasonable certainty, paid to replace or indemnify plaintiff, in whole or in part, for any past or future claimed economic loss, from any collateral source such as insurance, social security, worker's compensation or employee benefit programs.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

All or some of plaintiff's medical expenses have been paid by plaintiff's medical insurance carrier, or some other form of insurance, and plaintiff is not entitled to recover said medical expenses pursuant to § 6-5-522 of the Alabama Code.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**

Plaintiff's purported allegations of misrepresentation and fraud do not comply with Rule 9(b) of the Federal Rules of Civil Procedure, in that they fail to state a cause of action as a matter of law because, among other deficiencies, plaintiff fails to plead with specificity any false misrepresentation as to a material fact and/or reliance on the part of plaintiff upon any such material fact.

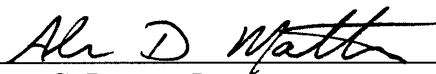
**THIRTIETH AFFIRMATIVE DEFENSE**

McCain is neither a manufacturer nor seller of Zyprexa®, and therefore she cannot be held liable under the Alabama Extended Manufacturer's Liability Doctrine.

WHEREFORE, defendant Yolanda McCain requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that McCain be awarded the costs, disbursements, and attorney's fees incurred in the defense of this action, and that she be granted any other relief to which she may be entitled.

**JURY DEMAND**

McCain demands a trial by jury for all issues in this action.



James C. Barton, Jr.

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Alan D. Mathis

Bar Number: ASB-8922-A59M

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Attorneys for defendant

Eli Lilly and Company

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Facsimile: (205) 458-9500

**OF COUNSEL**



**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the foregoing was served by first class mail, postage prepaid, on this 23<sup>rd</sup> day of May, 2006 upon the following:

E. Frank Woodson, Esq.  
Beasley, Allen, Crow, Methvin,  
Portis & Miles, P.C.  
P.O. Box 4160  
Montgomery, Alabama 36104

  
\_\_\_\_\_  
Of Counsel

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